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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PIETER CORNELIS LANGEVELD,
JACOBUS STARK, and PETRUS ANDREAS VAN PARIDON

Appeal 2008-0405
Application 10/089,874
Technology Center 1600

Decided: June 27, 2008

Before TONI R. SCHEINER, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-10 and 14-16. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The appealed claims are directed to a process for determining the presence or absence of an antimicrobial residue in a sample. According to the Specification, the presence of antimicrobial residues in foods is a growing concern (Spec. 1: 14-21). The Specification acknowledges that test methods to detect antimicrobial residues in foods were known in the prior art (Spec. 1-2). The Specification states that natural substances in food samples, such as milk, meat juice, and eggs can inhibit the growth of microorganisms and lead to false positives (Spec. 2: 14-26). "Natural inhibiting substances present in samples can be inactivated by heating, e.g., at 80°C for 10 minutes (Vermunt et. al., Netherlands Milk and Dairy Journal 47: (1) 31 - 40 (1993); Weisser, Tierarztliche Umschau 31: (6) 276 – 278 (1976))." (Spec. 2: 27-30). The claimed method involves "inactivating" such natural inhibiting substances ("natural disturbing compound").

Claims 1-10 and 14-16 are pending and appealed (App. Br. 2). The following rejections are on review:

1) Claims 1-10 and 16 under 35 U.S.C. § 102(b) as anticipated by Charm (U.S. Pat. No. 5,354,663, issued Oct. 11, 1994) (Ans. 4);

2) Claims 1-3, 8-10, and 16 under 35 U.S.C. § 102(b) as anticipated by Gist-Brocades (European Patent Published Application 0 005 891 A1 (Dec. 12, 1979) (Ans. 4-5);

3) Claims 1-3, 8-10, and 16 under 35 U.S.C. § 102(b) as anticipated by Lameris (U.S. Pat. No. 3,941,658, May 22, 1974) (Ans. 5-6); and

4) Claims 1-10 and 14-16 under 35 U.S.C. § 103(a) as obvious over Gist-Brocades and Charm (Ans. 6-7).

We select claims 1, 6, 7, 14, and 15 as representative. These claims (including claim 5 upon which claims 6 and 7 depend) read as follows:

> 1. A process for determining the presence or absence of an antimicrobial residue in a sample, which process comprises:
>
> (i) contacting the sample with a test suitable for determining the presence or absence of an antimicrobial residue in the sample;
>
> (ii) inactivating any natural disturbing compound, which is capable of inhibiting the test leading to a false positive result absent said inactivating step, present in the contacted sample and test; followed by
>
> (iii) incubating the contacted sample and test, to determine whether microbial growth occurs,
>
> whereby the absence of microbial growth indicates the presence of at least one antimicrobial residue.
>
> 5. A process according to claim 1, wherein step (ii) comprises heating the contacted sample and test for a sufficient time interval to inactivate natural disturbing substances present in the sample.
>
> 6. A process according to claim 5, wherein said heating is to a temperature of from 70°C to 100°C.
>
> 7. A process according to claim 5, wherein said heating is for from 2 to 20 minutes.
>
> 14. A process according to claim 5, wherein said heating is to a temperature of from 75°C to 85°C.
>
> 15. A process according to claim 5, wherein said heating is for from 10 to 15 minutes.

1. ANTICIPATION BY CHARM

Claims 1-10 and 16 stand rejected under 35 U.S.C. 102(b) as anticipated by Charm (Ans. 4).

Findings of Fact

The Charm Patent

1. Charm describes a test kit and method for detecting antimicrobial drugs in a sample, such as milk (Charm, Abstract; Ans. 4).

2. The test kit comprises a BST tablet containing Bacillus stearothermophilus (BST) spores which are sensitive to the drugs to be tested (Charm, at col. 2, ll. 4-8), a medium tablet which permits growth of the Bacillus bacteria (*id.* at col. 2, ll. 35-40), and a pH indicator to monitor the growth of the bacteria (*id.* at col. 4, ll. 5-10; Abstract).

3. Charm's "method comprises preheating a test sample to destroy natural inhibitors, cooling the sample, adding a BST tablet, rapidly heating to effect synchronization of BST spore germination,[1] adding a medium tablet, incubating and detecting the presence or absence of the antimicrobial drug" (Charm, Abstract). The growth of bacteria indicates the absence of antimicrobial drugs in a sample; the absence of bacterial growth indicates that antimicrobial drugs are present.

4. To destroy the natural inhibitors, the sample can be heated "to a temperature of about 100°C for about one to five minutes" (Charm, at col. 3, ll. 36-39; Ans. 4).

5. After combining with the BST table, the mixture is "rapidly heated to a defined temperature to heat shock the BST spores so as to affect generally synchronous germination of the BST spores. Generally, the rapid heating of the BST spores in the test sample is done to a temperature of about 100°C or more for about 0.1 to 2 minutes" (Charm, at col. 3, ll. 48-53; *see* Ans. 4).

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[1] The spores are first germinated and then the germinated spores develop into bacteria which are cultured in the nutrient medium.

6. In a preferred embodiment, the mixture of sample and test kit is placed in boiling water (i.e., 100°C) for 2 minutes to produce germination (Charm, at col. 8, ll. 40-44).

7. "The test container containing the test sample, BST and medium with the nutrients are then incubated, for example, at an incubation temperature of 65°C±1°C and incubation time for about 2 hours 45 minutes to 3 hours 15 minutes" (Charm, at col. 3, ll. 64-68).

Claim 1

8. Claim 1 is directed to a process "for determining the presence or absence of antimicrobial residue in a sample."

9. The process comprises three steps, numbered (i), (ii), and (iii).

10. Step (i) contacts the "sample" with a "test suitable for" detecting the antimicrobial residue.

11. Step (ii) comprises "inactivating any natural disturbing compound" present in the "sample and test" which is capable of producing a false positive.

12. Step (ii) is "followed by" step (iii).

13. Step (iii) incubates the sample and test "to determine whether microbial growth occurs."

14. The "absence of microbial growth indicates the presence" of an antimicrobial residue in the sample.

15. The phrase "inactivating any natural disturbing compound . . . present" in the sample as recited in step (ii) means inactivating whatever[2] natural

[2] Any: "2. whatever or whichever it may be . . . 3. in whatever quantity or number." *Random House Dictionary* 61 (1975).

disturbing compound is in the sample; the phrase does not require a natural disturbing compound to be present in the sample.

16. Step (ii) does not require all of the natural disturbing compound present in a sample to be inactivated (Ans. 4).

Application of the Charm Patent to the claims

17. Charm's method detects antimicrobial drugs in a sample (FF 1) as does the process of claim 1 (FF 8).

18. Charm describes combining the sample with a test kit for detecting the antimicrobial drug (FF 2, 5) which meets step (i) of the claimed method in which a "sample" is contacted with a "test suitable for" detecting the antimicrobial residue (FF 10).

19. Charm also describes heating to 100°C for 2 minutes (FF 5, 6) which are conditions described by Charm that would destroy natural inhibitors (FF 4).

20. Charm's step of heating the sample and test to 100°C for 2 minutes meets the limitation of step (ii) of claim 1 of "inactivating any natural disturbing compound."

21. After heating the sample and test to 100°C for 2 minutes, the mixture is incubated to determine microbial growth (FF 7) as in step (iii) of claim 1.

22. Charm describes a method which meets all three process limitations of claim 1 (FF 17-20).

Analysis

To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In this case, we agree with the Examiner's findings that Charm

describes a method that satisfies all the process limitations of claim 1 (*see* Ans. 4; as summarized in FF 17-22). Thus, we turn to Appellants' rebuttal arguments and evidence.

Appellants argue that the "inactivating" step (ii) of claim 1 is performed on both the sample and test (App. Br. 5). "In contrast, Charm teaches inactivating the sample alone (please see column 3, lines 33-35) and 'thereafter' (please see column 3, line 46) heating the inactivated sample having BST spores added thereto (please see column 3, lines 47-48)" (App. Br. 5; *see also* Reply Br. 7).

This argument is not persuasive. The Examiner relied upon Charm's heat shock step in which the BST spores are germinated by heat treatment for teaching step (ii) of claim 1 (Ans. 4). This step involves heating a mixture of spore (the "test") and sample to 100°C or more for about 0.1 to 2 minutes (FF 5); in a preferred embodiment, Charm heats to 100°C for 2 minutes (FF 6). While the purpose of such step is explicitly stated by Charm for "synchronous germination of the BST spores" (FF 5), the conditions are also those which would inactivate at least some natural inhibitor when present – as required by step (ii) of claim 1 (FF 4, 15, 16, 19).

Appellants assert that "Charm does not disclose destroying 'at least some of' the natural inhibitors in the sample in column 1, lines 32-39, as alleged in the Examiner's Answer. Charm states that the sample is heated 'to a temperature sufficiently high to destroy the natural *inhibitors* in the sample, and thereby enhancing the further sensitivity of the test . . . (emphasis added).' There is no mention in Charm that only 'some of' the natural inhibitors are destroyed. Thus, Charm does not indicate that any natural inhibitors remain after the heating step" (Reply Br. 6-7). Appellants

further argue that "Charm does not disclose or suggest any inactivating occurs in the spore-shocking heating step" (Reply Br. 7).

The Examiner has the better argument. Appellants do not point to any evidence that all the natural inhibitor would be destroyed in Charm's heating step. Since Charm teaches a range of times over which the inactivation step is conducted (FF 4, i.e., one to five minutes), we agree that it would have been reasonable to believe that with certain time periods (e.g., one minute) not all inhibitor would be inactivated by the heat treatment step. Nonetheless, as explained below, this finding is not necessary to conclude that Charm teaches step (ii) of the claimed method.

We do *not* interpret step (ii) to require that "natural disturbing compound" be present in the sample (FF 15). As indicated previously, we interpret "any" in step (ii) (FF 15) to mean *whatever* amount is present, which encompasses the situation in which no "natural disturbing compound" is present in the sample. Thus, Charm's heat shock step satisfies the limitation of step (ii) of "inactivating any natural disturbing compound – regardless of whether disturbing compounds are there to be inactivated. "An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989). If Appellants intend the claim to require the presence of a natural disturbing compound in the sample, the intent should be reflected in the explicit language of the claim.

In the Reply Brief, Appellants argue that the anticipation rejections should be reversed under *Perricone v. Medicis Pharm. Corp*, 432 F.3d 1368, 1372 (Fed. Cir. 2005), because "this case stands for the proposition that if

the benefits of the claimed steps or mechanisms of use are not found in the cited reference, then the prior art does not anticipate, inherently or otherwise" (Reply Br. 5). We do not agree. In *Perricone*, 432 F.3d at 1372, the court reversed the District Court as to one of the anticipation rejections because the cited prior art reference did not teach applying the lotion to sunburn as required by the claim, but instead taught it more broadly as being applied to a skin surface. Thus, the prior art did not teach all elements of the claimed invention.

For the foregoing reasons, we affirm the rejection of claim 1. Claims 2-10 and 16 fall with claim 1 because separate reasons for their patentability were not provided. 37 C.F.R. § 41.37(c)(1)(vii).

2. ANTICIPATION BY GIST-BROCADES

Claims 1-3, 8-10, and 16 stand rejected under 35 U.S.C. § 102(b) as anticipated by Gist-Brocades (Ans. 4-5).

Findings of Fact

23. Gist-Brocades describes a process for determining residues of antibiotics in biological liquids, such as milk, meat juice, serum, and urine (Gist-Brocades, at 1, ll. 1-3).

24. Spores of a microorganism are introduced into agar which is then allowed to solidify in a test tube (Gist-Brocades, at 2, ll. 10-20).

25. The test sample is placed on top of the agar in the test tube and "left there or removed after a sufficiently long time . . . for the diffusion of the residues of antibiotics" into the agar (Gist-Brocades, at 5, ll. 18-20).

26. "[T]he contents of the test tube are incubated at or near the optimal temperature for the microorganisms during a predetermined period after

which . . . the presence or absence of an antibiotic" is observed" (Gist-Brocades, at 5, ll. 21-24).

27. Gist-Brocades describes prior art in which Bacillus stearothermophilus was cultured at about 60°C (Gist-Brocades, at 1, ll. 18-19).

Analysis

The Examiner contends that the teaching in Gist-Brocades of culturing bacteria at 60°C for an extended period of time (FF 27) meets the inactivating step of claim 1, step (ii) (Ans. 5). Appellants contend that Gist-Brocades does not disclose an inactivating step and the comparative results in Example 1 of the Specification show that inactivation does not necessarily occur in Gist-Brocades (App. Br. 5-6).

A "prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005). Once "the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). In this case, there is insufficient evidence that the 60°C culturing step of Gist-Brocades would inactivate a natural inhibitor as required by claim 1.

The Examiner states that Gist-Brocades describes a "product [which] has been sold commercially since the seventies. If the method of Gist-Brocades did not result in the inactivation of any natural disturbing compounds in the samples, the method of using the product would not work, and the product would not have made it to market" (Ans. 8). However, the

Examiner has introduced no evidence that the "commercial product" is the same as the process described in Gist-Brocades nor that the product's market success is tied to its ability to inactivate natural inhibitors. Moreover, the Examiner has provided no evidence that would have led persons of skill in the art to reasonably believe that the conditions taught by Gist-Brocades could result in "inactivating any natural disturbing compound" as recited in claim 1.

We reverse the rejection of claim 1 and dependent claims 2, 3, 8-10, and 16.

3. ANTICIPATION BY LAMERIS

Claims 1-3, 8-10, and 16 stand rejected under 35 U.S.C. § 102(b) as anticipated by Lameris (Ans. 5-6).

Findings of Fact

The Lameris Patent

28. Lameris teaches a method for the rapid determination of the presence or absence of antibiotic residues in liquids (Lameris, Abstract).

29. Bacterial spores are introduced into agar and the agar is solidified; the solidified agar is contacted with a sample to determine whether the sample contains an antibiotic residue that inhibits microorganism growth (Lameris, Abstract).

30. The sample, spores, and other components needed for microorganism growth and detection, are incubated together (Lameris, at col. 5, ll. 34-64).

31. "When using spores of *Bacillus stearothermophilus* var. *calidolactis*, suitable incubation temperatures are about 55° to 70°C" (Lameris, at col. 5, ll. 65-67) from about 1½ to 4 hours (*id.* at col. 5, l. 67 to col. 6, l. 2). Growth

of the bacteria indicates antibiotic residues are absent from the liquid; bacterial growth inhibition indicates antibiotic is present.

Application of the Lameris Patent to the claim

32. Lameris describes a method of determining the presence or absence of antibiotic residues in liquids – the same objective as in claim 1 (FF 8).

33. Lameris's method involves contacting a sample and components for microorganism growth (FF 29-31) – i.e., a "test suitable for determining the presence or absence of an antimicrobial residue" as in step (i) of claim 1 (FF 10).

34. The combination of sample and test are incubated at temperature range of 55° to 70°C (FF 30).

35. The Specification teaches that inactivation of natural antimicrobial compounds ("natural disturbing compound" of instant claim 1) can be achieved by heating "for from about 2 to 20 minutes at from 70°C to 100°C" (Spec. 7, ll. 21-22).

36. Thus, based on the teaching in the Specification (FF 35), heating the combination at 70°C as taught by Lameris (FF 31) would result in inactivation of a "natural disturbing compound" – meeting the limitations of claim 1's step (ii) (FF 11) (*see* Ans. 6).

37. Lameris also teaches incubating the combination to detect microbial growth (FF 31), as required by step (iii) of claim 1.

38. In sum, Lameris describes a method which meets all three process limitations of claim 1 (*see* FF 17-20 for summary of claim limitations).

Analysis

Anticipation requires a teaching of every limitation of the claimed invention in a single prior art reference, arranged as in the claim. *Karsten Mfg. Corp.*, 242 F.3d at 1383. In this case, we agree with the Examiner's findings that Lameris describes a method that satisfies all the limitations of claim 1 (FF 32-38; *see* Ans. 5-6). Thus, we turn to Appellants' rebuttal arguments and evidence.

Appellants argue that "Lameris' cited conditions will not necessarily inactivate any natural disturbing compound. The Examiner has not provided evidence or established that, under Lameris' particular conditions, inactivation will necessarily take place" (App. Br. 6).

We disagree. Lameris discloses incubation at about 70°C, a value at which the Specification teaches that inactivation takes place (FF 35). Inherent anticipation does not require intent or recognition that a prior art process achieve a result which is claimed. "Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." *MEHL/Biophile International Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). Thus, when the Lameris process is carried at 70°C, as set forth in Appellants' Specification, inactivation would occur, even if unrecognized by persons of ordinarily skill in the art.

Appellants argue that no evidence has been presented that inactivation would "necessarily" occur (App. Br. 6-7), but we do not agree. The Examiner specifically points to instant claim 6 which recites a temperature range that includes 70°C (*see* also FF 35; Spec. 7, ll. 21-22, which describes

70°C as effective for inactivating natural antimicrobial compounds). Thus, there is evidence of record that inactivation would *necessarily* occur when the teachings of Lameris are followed. Appellants have not identified any defect in this evidence. As noted by the Examiner, no temperature limitations are recited in claim 1 that would distinguish it from Lameris (Ans. 6).

Appellants also assert that "Lameris does not disclose that inactivation of any natural disturbing compounds necessarily takes places before the incubating step as claimed" (Reply Br. 12).

This argument is not persuasive. Claim 1 recites that the inactivating step (ii) is "followed by" the incubation step (iii) (FF 11-12). In other words, inactivation is before incubation. However, as pointed out by the Examiner, there is no requirement in claim 1 that the inactivation step occur at a different temperature than the incubation step nor that the two steps occurs discretely – rather than overlapping. Thus, at least an initial part of the incubation period during which the disturbing compounds are inactivated would be considered an inactivation step as in claim 1. The remaining incubation period would follow inactivation, and thus satisfy the limitation of an incubation step (iii) of claim 1.

For the foregoing reasons, we affirm the rejection of claim 1. Claims 2, 3, 8-10, and 16 fall with claim 1 because separate reasons for their patentability were not provided. 37 C.F.R. § 41.37(c)(1)(vii).

4. OBVIOUSNESS OVER GIST-BROCADES AND CHARM

Claims 1-10 and 14-16 stand rejection under 35 U.S.C. §103(a) as obvious over Gist-Brocades and Charm (Ans. 6-7).

As we have affirmed the rejection of claims 1-10 and 16 as anticipated by Charm, we only consider the separate arguments for claim 6, 7, 14, and 15. Appellants argue that there was "no motivation to arrive at . . . the time disclosed in present claims 6-7 and 14-15 (Reply Br. 12).

As for claim 6 (which depends on claim 5) which specifies that the "heating is to temperature of from 70°C to 100°C", we note that Charm teaches heating at 100°C for 2 minutes (FF 5). Thus, for the same reasons we affirmed the rejection as anticipated by Charm (*see supra*), we conclude that claim 6 is also obvious over Charm's disclosure. Likewise, Charm's teaching of heating for 2 minutes (FF 5) meets claim 7's limitation that the "heating is from 2 to 20 minutes." Thus, we also affirm the rejection of claim 7.

Claims 14 and 15 require that the "heating [in step (ii)] is to a temperature of from 75°C to 85°C" and "for from 10 to 15 minutes", respectively. The Examiner asserts:

> use an inactivating temperature of 100°C, for a total time of 1.1-7 minutes, while Appellants use an inactivating temperature of 75 - 85°C for 10-20 minutes, but Appellants note in the specification that "any other temperature/time treatment, which is sufficient to obtain said effects, can be used" (see p. 8, lines 15-17). It would have been obvious to one of ordinary skill in the art that, in a heat inactivation step, compared to heating at a particular temperature for a particular length of time, heating at a lower temperature for a longer period of time would also have achieved heat inactivation, especially in a biological system where the lower temperature is such that biological activities do not occur and proteins are denatured.

(Ans. 12).

We agree with Appellants that it improper to rely on Appellants' Specification to arrive at the claimed temperatures (Reply Br. 12). We also

agree that there would have been no reasonable expectation of success that the lower temperature of claim 14 would achieve inactivation in view of Charm's teaching of a temperature of 100°C for spore germination (FF 6), which is the part of the disclosure relied upon by the Examiner for this step (see FF 6). Thus, we reverse the rejection of claim 14.

Claim 15 is drawn to a heating period of 10 to 15 minutes to accomplish inactivation. The Examiner has not provided sufficient evidence that heating for this time period would have been suggested from Charm's disclosure of heating for about 0.1 to 2 minutes to achieve spore germination (FF 5, 6), which is the part of the Charm relied upon for teaching claim 1's step (ii). Thus, we reverse the rejection of claim 15.

CONCLUSION

1) The rejection of 1-10 and 16 as anticipated by Charm is affirmed;
2) the rejection of claims 1-3, 8-10, and 16 as anticipated by Gist-Brocades is reversed;
3) the rejection of claims 1-3, 8-10, and 16 as anticipated by Lameris is affirmed;
4) the rejection of claims 1-10 and 16 as obvious over Gist-Brocades and Charm is affirmed; and
5) the rejection of claims 14 and 15 as obvious over Gist-Brocades and Charm is reversed.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

dm

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